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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,663	11/13/2003	Kuo-Hsiung Lee	5470-397	2599

7590

05/12/2005

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EXAMINER

OWENS, AMELIA A

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,663

Applicant(s)

LEE ET AL.

Examiner

Amelia A. Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 11-21 is/are rejected.
- 7) ☒ Claim(s) 5-10 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claims 1-21 are pending. No drawings were filed. No foreign priority claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,4,11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ying-Jie et al CA 130:296539 that teach species according to the invention. See RN 223428-25-9 at page 42 of search notes. Note X=NH; R1= CH₂(loweralkyl); Y=C(O)O; R2=H; n=0; R3 =phenyl(aryl). The compounds have anticancer activity.

Claims 1,4,11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al CA 128:110425 that teach species according to invention. See RN 118356-06-02 at page 44 of search notes. Note X=S; R1=link; Y=none; n=o; R2=H; R3=alkyl.

Claims 1,4,11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Anyanwutaku et al CA 124:331692 which teach species according to the invention. See RN 176702-25-5 at page 52 of search notes. The compounds have anticancer activity.

Claims 1,4,11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan-guang et al CA 125:275518 which teach species according to the invention. See RN 182206-88-8 at page 48/49 of search notes. Note X=NH; R1= CH₂(loweralkyl); Y=C(O)O; R2=H; n=0; R3 = Me(alkyl). The compounds have anticancer activity.

Claims 1-4,11-13, 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho et al CA 124:249647 that teach species according to the invention. See RN 122036-95-7

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@p.53; RN127882-57-9 @ p. 54; RN 127882-59-1 @ p.54/55 of search notes. The compounds have anticancer activity. Note in particular that for RN 127882-59-1 that X=NH; R1=phenyl.

Several other references teach species according to the invention. See CA 121:35138 RN 155325-26-1 @ p.61; CA 120:323053 RN 150060-11-0 @ p.67; CA 118:204718 RN147199-55-1 @p.72/73; CA118:191417 RN 102306-95-6 @p.74; CA 118:124260 RN 118356-06-2 @ p.75, RN146132-59-4 @p.76; CA 118:6779 RN 144780-98-3 @ p.77; CA 117:124086 RN 143247-78-3 @p.81, RN 143247-79-4 @p.81/82, RN 143247-82-9 @ p.82/83.

Claims, 5-10, 14-21 are not included in the rejection as the specific limitations are not taught/fairly suggested by the reference. Note the reference does not teach the specific cancers.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to

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make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention: The nature of the invention is the method of treating cancer, which has been known by the skilled artisan in the field to be highly unpredictable, and ordinarily no general umbrella extrapolation of any specific date should be made. See claim 13.

The state of the prior art and predictability: The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, cancer treatment has been known to be compound an disease specific, that is a particular compound or class of compound can be useful in treating a particular type or class of cancer.

The amount of guidance and working examples: Several compounds according to the invention have been made. Primary screening tests such as those exemplified in the specification ordinary qualifies the compound for further testing but does not offer therapeutic value unless continuous testing reveal therapeutic index. Such screening tests ordinarily cannot be extrapolated to multiple cancer type without further testing. Applicants are claiming to treat all known cancer and all cancers yet to be discovered and such invention is wholly inoperable.

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Thus, the specification fails to provide sufficient support of the broad use of the compounds of claim 1 for the treatment of all known and yet to be discovered cancers, nor the specific cancers of the claims. As a result necessitating one of ordinary skill to perform an exhaustive search for which cancers can be treated by which compound of claim 1 in order to practice the claimed invention.

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, one of ordinary skill in the art would have to engage in undue experimentation to test which cancers can be treated by the compounds of the instant claims, with no assurance of success.

This rejection can be overcome by deleting the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The transitional term 'comprising', which is synonymous with 'including', 'containing', or 'characterized by', is inclusive or open-ended and does not exclude additional unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). See MPEP 211.03.

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Claims 5-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5,11-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3,5,11-20,22 of U.S. Patent No. 6,566,393 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same generic concept.

Lee et al generically disclose podophyllotoxin compounds as are instantly claimed and their use to treat cancer, in particular applicants' cancers. See claims 1.

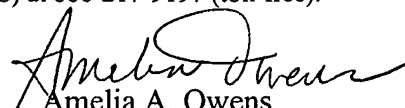
One of ordinary skill in the art would thus be motivated to prepare compounds from under the Lee et al genus in order to obtain additional anticancer agents. Also, one of ordinary skill in the art would be motivated to prepare compounds structurally similar to those of Lee et al in the expectation of obtaining a useful compound to treat cancer as compounds structurally similar in structure are expected to have similar properties. The level of skill in the art is further reflected in *In re Lohr* 137 USPQ 548 at 549 (CCPA 1963), and in *In re Payne* 204 USPQ 249 at 254 (CCPA 1979).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Amelia A. Owens
Primary Examiner
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